

# EXHIBIT E

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ST. CLAIR INTELLECTUAL PROPERTY CONSULTANTS, INC.,	:
	:
Plaintiff,	:
	:
v.	:Civil Action No. 04-1436-JJF
	:
SAMSUNG ELECTRONICS CO., LTD.,	:
SAMSUNG ELECTRONICS AMERICA, INC.,	:
SAMSUNG TELECOMMUNICATIONS	:
AMERICA, L.P., MATSUSHITA ELECTRIC	:
INDUSTRIAL CO., LTD., MATSUSHITA	:
ELECTRIC CORPORATION OF AMERICA,	:
VICTOR COMPANY OF JAPAN, LTD., JVC	:
COMPANY OF AMERICA, NOKIA	:
CORPORATION, NOKIA, INC.,	:
HEWLETT-PACKARD COMPANY, and	:
EASTMAN KODAK COMPANY,	:
	:
Defendants.	:

MEMORANDUM ORDER

Pending before the Court is Defendants' Joint Motion To Stay Action Pending Resolution Of Patent Ownership Dispute Between Plaintiff And Mirage Systems, Inc. (D.I. 30), Plaintiff's Motion To Bifurcate And Expeditedly Proceed With The Ownership Issue In The Present Action (D.I. 39), and Plaintiff's Motion For Leave To File A Supplemental Brief To Plaintiff's Answering Brief To Defendants' Joint Motion To Stay Action Pending Resolution Of Patent Ownership Dispute Between St. Clair And Mirage Systems, Inc. (D.I. 42). For the reasons discussed, Defendants' motion to stay (D.I. 30) and Plaintiff's motion for leave to file (D.I. 42) will be granted. Plaintiff's motion to bifurcate and expeditedly proceed (D.I. 39) will be denied with leave to

renew.

## I. BACKGROUND

On November 9, 2004, Plaintiff filed its Complaint (D.I. 1), alleging that Defendants infringed four of its patents: United States Patent Nos. 5,138,459 ("the '459 patent"), 6,094,219 ("the '219 patent"), 6,233,010 ("the '010 patent"), and 6,323,899 ("the '899 patent"). On April 12, 2005, Mirage Systems, Inc. ("Mirage") filed a lawsuit against Plaintiff in a California state court ("the California lawsuit"), alleging that it owns the patents-in-suit by way of employment agreements entered into with the inventors. In response to the California lawsuit, Plaintiff filed a declaratory judgment action against Mirage and two of its officers in this Court (05-273-JJF) ("the declaratory judgment action"), seeking a declaration of ownership of the patents-in-suit and two other patents.

On May 19, 2005, Defendants filed a motion to stay this case pending resolution of the patent ownership dispute between Plaintiff and Mirage. (D.I. 30). In response, Plaintiff filed a motion to bifurcate the ownership issue from the infringement issues and expeditiously proceed with the ownership issue in this case (D.I. 39). On June 10, 2005, Eastman Kodak Company ("Kodak"), a defendant in this case, acquired any ownership rights Mirage allegedly possesses in the patents-in-suit. Plaintiff filed a motion for leave to supplement its answering

brief to include this fact and arguments relating to it. (D.I. 42). Upon learning that Kodak had acquired Mirage's rights, all Defendants, with the exception of Kodak, supported Plaintiff's motion to bifurcate. (D.I. 44, 45). On June 20, 2005, the United States Patent and Trademark Office ("USPTO") issued office actions relating to a reexamination of two of the patents-in-suit. Following the USPTO's actions, all Defendants again supported a stay in this case. (D.I. 52).

## **II. PARTIES' CONTENTIONS**

Defendants contend that a stay is appropriate because discovery has not begun, a trial date has not been set, and Plaintiff will not be unduly prejudiced by the stay. Defendants request a stay to allow the ownership issue to be resolved and to await a decision from the patent reexaminations.

Plaintiff contends that a stay is inappropriate in this case because this case is proceeding at a faster rate than the other two cases, and, therefore, resolving the ownership dispute in this case is the most efficient way to settle the issue. Plaintiff further contends that a stay is inappropriate because the parties now involved in the ownership dispute are before the Court in this case, since Kodak now owns the patents-in-suit.

### III. DISCUSSION

The decision to grant or deny a stay is within the court's broad discretion. Bechtel Corp. v. Laborers' Int'l Union, 544 F.2d 1207, 1215 (3d Cir. 1976). In determining whether a stay is appropriate, a court should "weigh the competing interests of the parties and attempt to maintain an even balance." Dentsply Int'l Inc. v. Kerr Mfg. Co., 734 F.Supp. 656, 658 (D. Del. 1990). In weighing the interests involved, courts are generally guided by such factors as (1) whether a stay will simplify the issues raised by the parties; (2) whether discovery is complete and a trial date has been set; and (3) whether a stay would unduly prejudice the non-movant. Gioello Enters. Ltd. v. Mattel, Inc., 2001 WL 125340 (D. Del. Jan. 29, 2001); United Sweetener USA, Inc. v. Nutrasweet Co., 766 F.Supp. 212, 217 (D. Del. 1991). In balancing these factors, courts must be particularly mindful of the consequences of the stay on the other parties. Dentsply Int'l Inc., 734 F.Supp. at 658.

The Court concludes that a stay is appropriate for several reasons. First, discovery has not begun. Second, a stay will allow the ownership issue to be resolved in the declaratory judgment action without the complications of other Defendants. Finally, Plaintiff will not be unduly prejudiced by the granting of the stay. The stay may well save time and expense, not only for Defendants, but for Plaintiff. For example, if the Court did

not grant a stay, Plaintiff could be required to litigate the ownership issue in three different cases. Accordingly, the Court will grant Defendants' motion to stay (D.I. 30) and Plaintiff's motion for leave to file (D.I. 42). The Court, however, will deny with leave to renew Plaintiff's motion to bifurcate and expeditiously proceed (D.I. 39).

ORDER

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. Defendants' Joint Motion To Stay Action Pending Resolution Of Patent Ownership Dispute Between Plaintiff And Mirage Systems, Inc. (D.I. 30) is GRANTED.
2. Plaintiff's Motion To Bifurcate And Expeditiously Proceed With The Ownership Issue In The Present Action (D.I. 39) is DENIED WITH LEAVE TO RENEW.
2. Plaintiff's Motion For Leave To File A Supplemental Brief To Plaintiff's Answering Brief To Defendants' Joint Motion To Stay Action Pending Resolution Of Patent Ownership Dispute Between St. Clair And Mirage Systems, Inc. (D.I. 42) is GRANTED.

February 14, 2006

  
UNITED STATES DISTRICT JUDGE

## EXHIBIT F

# HellerEhrman LLP

January 17, 2006

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*Via Email and U.S. Mail*

Edward Han  
Howrey LLP  
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Washington, DC 20004

Re: *Jang v. Boston Scientific, et al.*, C.D. Cal. Case No. ED CV 05-00426 VAP SGLx

Dear Mr. Han:

As you know, notwithstanding Scimed's and Boston Scientific's material breach of the assignment agreement with Dr. Jang, notwithstanding Scimed's and Boston Scientific's unconscionable and untenable assertion that the assignment agreement somehow conveyed ownership of Dr. Jang's balloon catheter patents to Scimed, and notwithstanding Dr. Jang's rescission of the assignment agreement, all of which, collectively and independently, relieves Dr. Jang of any obligations under the assignment agreement, including the obligation to cooperate in litigation contained in Paragraph 7.3(b), Dr. Jang voluntarily provided material assistance to Scimed and Boston Scientific in the J&J litigation. Dr. Jang similarly stands ready to assist with the infringement suit against Conor Medsystems, if the district court permits that suit to proceed in the face of Dr. Jang's rescission of the parties' agreements.

Dr. Jang's willingness to assist Scimed and Boston Scientific in the J&J matter and his willingness to assist Scimed and Boston Scientific in the Conor Medsystems matter is and always has been without prejudice to Dr. Jang's position in his lawsuit against Scimed and Boston Scientific that the assignment agreement has been rescinded. As a consequence of that rescission, which relates back to the date the assignment agreement and related documents were executed (as I am sure Boston Scientific and Scimed realize), any and all damages or settlement proceeds obtained by Scimed or Boston Scientific in either lawsuit will belong to Dr. Jang as a matter of law. For reasons known only to your clients, they elected to proceed with the J&J litigation and initiate the Conor litigation with full knowledge of Dr. Jang's rescission of the assignment agreement. They did not ask Dr. Jang's permission to proceed in either action, but instead proceeded unilaterally as though they were the owners of the claims being asserted. Having done so, they must realize that they will be constructive

HellerEhrman LLP

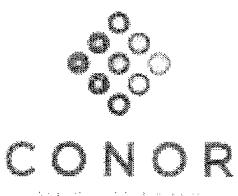
January 17, 2006  
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trustees for Dr. Jang of any proceeds they may recover in either lawsuit once judgment is entered in Dr. Jang's favor in *Jang v. Boston Scientific et al.*

Very truly yours,

  
Paul A. Rose

# EXHIBIT G



## Company : Press Release

### Conor Medsystems Receives CE Mark for CoStar(TM) Drug-Eluting Stent

First Reservoir-Based Controlled-Release Drug Delivery Stent with Bioresorbable Polymer to be Launched in Europe

MENLO PARK, Calif., Feb. 17 /PRNewswire-FirstCall/ -- Conor Medsystems, Inc., (Nasdaq: CONR), a pioneer in next generation drug-eluting stents, today announced that it received Conformite Europeen (CE) Mark approval for its CoStar(TM) cobalt chromium paclitaxel-eluting stent for the treatment of coronary artery disease. CE Mark approval enables Conor Medsystems to commercialize its CoStar stent in the European Union and other countries accepting CE Mark. Beginning immediately, Conor's CoStar stent will be marketed and distributed in these markets by Biotronik AG, a leading manufacturer and global distributor of devices in the area of interventional cardiology.

"Clinical studies of the CoStar stent have shown significant patient benefits and demonstrated the importance of controlled drug delivery for the treatment of restenosis," said Keith D. Dawkins, M.D., FRCP, FACC, Director of Cardiac Interventions at Southampton University Hospital, Southampton, United Kingdom. "In addition to positive clinical results, the CoStar stent has consistently demonstrated an excellent safety profile, and the use of bioresorbable polymers ensures that no permanent polymer residue or drug remains at the target site."

In contrast to conventional surface-coated stents, Conor's CoStar cobalt chromium paclitaxel-eluting coronary stent has been specifically designed for vascular drug delivery. The CoStar stent differs from conventional surface-coated drug-eluting stents as it is not coated. Instead, Conor's stent incorporates hundreds of small holes, each acting as a reservoir into which drug-polymer compositions can be loaded. In addition, the CoStar stent uses bioresorbable polymers that are absorbed by the body after the drug is released, leaving no permanent residual polymers or drug at the target site.

The British Standards Institute (BSI) issued CE Mark approval of the CoStar stent based on a review of the preclinical and clinical data indicating the safety and efficacy of the CoStar stent in the treatment of coronary artery disease and reducing the rate of restenosis. In particular, CE Mark approval of Conor's CoStar stent was supported by data from the company's pivotal EuroSTAR clinical trial, as well as other supporting clinical trials including the PISCES and COSTAR I studies. The CoStar stent is being commercially manufactured at Conor's ISO-certified facility in Ireland.

"We are very pleased to achieve this significant milestone and begin commercialization of our CoStar stent in Europe," said Azin Parhizgar, Ph.D., Chief Operating Officer of Conor. "We believe that the unique design and technology of Conor's drug-eluting stent represents a significant innovation in the treatment of patients with coronary artery disease and that the use of Conor's CoStar stent will lead to improved patient care."

"With more than 800,000 angioplasty procedures performed each year in Europe and the market growing at a rate of almost 10 percent annually, there is tremendous commercial potential for Conor's CoStar stent," said Marlow Janssen, Vice President, Sales and Marketing of Biotronik Vascular Intervention, Biotronik AG. "We are pleased to begin marketing and distribution of Conor's pioneering vascular drug delivery technology."

Biotronik has the right to market and distribute the CoStar stent in Europe, Latin America and certain countries in Asia. Interventional Technologies, Pvt., Ltd. has the right to distribute the CoStar stent in India, and affiliates of St. Jude Medical, Inc. have the right to distribute the CoStar stent in Japan and several countries in the Pacific Rim, subject to receipt of regulatory approval.

Conor is currently conducting a U.S. pivotal clinical trial, COSTAR II, to support its application for U.S. regulatory approval of the CoStar stent.

The CoStar stent is not available for sale in the United States where it is an investigational device limited by law to investigational use.

#### About Conor Medsystems

Conor Medsystems, Inc. develops innovative controlled vascular drug delivery technologies, and has initially focused on the development of drug- eluting stents to treat coronary artery disease. For further information on Conor Medsystems and controlled vascular delivery, visit [www.conormed.com](http://www.conormed.com).

#### About Biotronik

Biotronik is a leading European manufacturer of biomedical technology with a worldwide market presence. The company offers a complete line of products for diagnosis, treatment, and advanced therapy support in the areas of cardiac rhythm management, electrophysiology and vascular intervention. The field of vascular intervention consists of guide wires, balloon catheters and stent systems for coronary and peripheral applications. For more information, visit Biotronik's website at [www.biotronik.com](http://www.biotronik.com).

This press release contains certain forward-looking statements that involve risks and uncertainties, including without limitation, the statements related to the marketing and distribution of, and the commercial potential for, the company's CoStar stent and the use of company's CoStar stent leading to improved patient care. All forward-looking statements and other information included in this press release are based on information available to Conor Medsystems as of the date hereof, and the company assumes no obligation to update any such forward-looking statements or information. The company's actual results could differ materially from those described in the company's forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in detail under the heading "Risk Factors" in the company's Quarterly Report on Form 10- Q for the quarter ended September 30, 2005 filed with the SEC on November 14, 2005, including (i) risks related to the commercialization of company's CoStar stent, including, among other things (a) the risk that the company's CoStar stent may never achieve market acceptance, (b) the risk that the company's manufacturing facilities may be unable to provide an adequate supply of its CoStar stent, (c) the risk that the loss of the company's single source suppliers could interrupt or delay the company's commercialization efforts, (d) the risk that company's distributors' sales and marketing strategies may fail to generate meaningful revenues from sales of the company's CoStar stent, (e) the risk that the company may fail to comply with ongoing regulatory requirements, or that the company may experience unanticipated problems with its CoStar stent, (f) the risk that the company may not obtain adequate levels of reimbursement for its CoStar stent by third-party payors and (g) the risk that the company's competitors may develop and market products that are safer and more effective than the CoStar stent; (ii) risks related to patent infringement, including, among other things, (a) the risk that if any patent infringement claims or other intellectual property claims against the company are successful, the company may, among other things (1) be enjoined from, or required to cease, the development, manufacture, use and sale of products, including the company's CoStar stent, that infringe the patent rights of others, (2) be required to expend significant resources to redesign its technology so that it does not infringe others' patent rights, which may not be possible, and/or (3) be required to obtain licenses to the infringed intellectual property, which may not be available to the company on acceptable terms, or at all, and (b) the risk that intellectual property litigation against the company could significantly disrupt the company's development and commercialization efforts, divert management's attention and quickly consume the company's financial resources; and (iii) the risk that clinical results reported to date may not be indicative of future clinical results and that longer-term results the company obtains with its CoStar stent may not show similar effectiveness. The risks and other factors discussed above should be considered only in connection with the fully discussed risks and other factors discussed in detail in the company's periodic reports filed with the SEC, including the company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005.

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# EXHIBIT H

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

27  
ORIGINAL

CORDIS CORPORATION, )  
Plaintiff, )  
v. ) C.A. No. 03-27-SLR  
BOSTON SCIENTIFIC CORPORATION )  
and SCIMED LIFE SYSTEMS, INC., )  
Defendants. )

**DEFENDANTS' PRELIMINARY RESPONSE TO  
PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION**

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Dated: March 14, 2003

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As instructed by the Court, defendants Boston Scientific Corporation and Scimed Life Systems, Inc. (collectively "BSC") hereby provide this preliminary response to plaintiff's motion for a preliminary injunction. For at least the reasons highlighted below, once the Court has had a chance to consider all of the facts and legal issues on a fully developed record, and has conducted a preliminary injunction hearing, BSC has confidence that Cordis will not be able to justify the extraordinary relief it seeks.

## I. INTRODUCTION

Cordis cannot establish any of the four factors required for a preliminary injunction. Cordis is not likely to succeed on the merits. It would not be irreparably harmed absent an injunction. The balance of hardships does not tip in Cordis' favor. And the public interest would not be served by its requested injunction.

Cordis is not likely to succeed on the merits because, *inter alia*, it cannot prove infringement under this Court's existing claim constructions. Moreover, construction of previously unexamined aspects of claim limitations such as "thin-walled" and "wall surface" should provide additional bases for non-infringement. And the claim limitation "slot" would provide yet another basis for non-infringement, should the Court revisit its construction of that limitation.

Cordis is also unlikely to sustain the validity of any asserted patent claim. To prevail on infringement, Cordis must stretch its patent claims to encompass subject matter that Dr. PalmaZ neither invented, described nor enabled. Such manipulation is prohibited, and violates the fundamental doctrine that a patent cannot claim what an inventor has not conceived.

Given that Cordis is unlikely to succeed on the merits, no irreparable harm can be presumed. But even if it were, such a presumption would be rebutted by, *inter alia*: (1) Cordis' sixteen-month delay in seeking a preliminary injunction; (2) the fact that Cordis has offered to

license and licensed the '762 patent; (3) the existence of non-infringing alternatives; and (4) the adequacy of monetary damages to compensate Cordis for any infringement.

Cordis' inability to prove the requisite likelihood of success on the merits and irreparable harm will be enough to warrant denial of its motion. But Cordis will fail with respect to the other preliminary injunction factors as well.

The balance of hardships tips in favor of BSC, not Cordis. For example – having waited for over sixteen months while BSC ramped up its EXPRESS stent manufacturing line in Minnesota – Cordis' requested injunction would shut that line down completely and eliminate hundreds of jobs. Cordis would not suffer any similar hardship. While Cordis may assert a possible loss of income and market share, such a loss cannot compare to idling a manufacturing line and hundreds of workers, especially when BSC can adequately address any such loss with monetary damages.

Lastly, Cordis cannot establish that its requested injunction is in the public interest. Relying on perfunctory pronouncements regarding a public interest in the patent system, Cordis wholly ignores the public's true interest in this case: a competitive medical device market that allows patients and health care professionals to choose the safest and most effective treatment possible in each case.

The United States Food and Drug Administration ("FDA") has already delayed approval of Cordis' drug-eluting stent. Cordis has not yet revealed the reason for this delay. But the drug Cordis uses to coat its stent has recently caused a number of deaths at higher doses in other applications. And the stent Cordis coats with this drug has been publicly criticized by doctors as, among other things, "a lousy base stent" and incompatible with the type of vascular

damage best addressed by its drug coating. In short, Cordis pairs the wrong drug with the wrong stent and asks this Court to deny the public a choice. That is not in the public interest.

Cordis cannot establish any, much less all, of the four factors required for a preliminary injunction. Through further investigation and discovery in this action, BSC intends to explore each of Cordis' failures of proof and develop each of the issues highlighted in this preliminary response. This investigation and discovery may uncover additional issues as well, and BSC will present complete information in its final response to plaintiff's motion and at the preliminary injunction hearing.

## II. BACKGROUND

BSC began the process for obtaining FDA approval to sell EXPRESS stents in the United States on April 11, 2001. By June 13, 2001, patients in the United States were receiving EXPRESS stents in clinical studies. Each of those milestones was the subject of a BSC press release, and Cordis knew or should have known of it.

Thereafter, BSC received regulatory approval to sell EXPRESS stents in Europe and began such sale by September 24, 2001. BSC issued a press release that day confirming the European launch. (Exhibit A) By that time, Boston Scientific CEO Jim Tobin had already disclosed in the *St. Paul Pioneer Press* that EXPRESS stents to be sold in Europe would be made in the United States. (Exhibit B) Given these publications, Cordis knew or should have known that BSC was making EXPRESS stents in the United States by September 24, 2001.

In addition to the publicly disclosed use of EXPRESS stents in the United States since June 13, 2001 – and the publicly disclosed manufacture of EXPRESS stents in the United States since at least September 24, 2001 – BSC began selling these stents in the United States immediately after the FDA approved them on September 12, 2002. This approval was the subject of another BSC press release (Exhibit C), and Cordis was certainly aware of it.

Despite the public disclosure of all of this information regarding the EXPRESS stent, Cordis did not file an action for infringement until January 13, 2003. Cordis did not move for a preliminary injunction at that time. That came later still. In total, Cordis delayed for over sixteen months before moving for a preliminary injunction.

In an attempt to divert attention from its delay and inability to establish any of the four preliminary injunction factors, Cordis goes on at length in its brief regarding the future prospects for drug-eluting stents currently being evaluated by the FDA. BSC will investigate Cordis' assertions in this area and address them in detail in its final brief. In this preliminary response, however, BSC notes that Cordis' U.S. Patent No. 4,739,762 (hereinafter "the '762 patent") has nothing to do with drug-eluting technology.

Cordis asks this Court to grant it the exclusive right to sell drug-eluting stents in the United States, but the '762 patent has no such scope. A classic example of overreaching, Cordis seeks to corner the market for drug-eluting stents with a patent on bare-metal stents that the industry left behind long ago. Equity should not reward such tactics.

That is especially true where, as here, Cordis' proposed drug-eluting stent system is the subject of three separate claims of patent infringement. The first such claim, pending since 2002 in the Northern District of California, addresses infringing stent delivery systems that Cordis proposes to use with its drug-eluting stent. The second such claim, a counterclaim in this action, addresses the infringing architecture of Cordis' drug-eluting stent. And the third such claim, filed recently in this Court as a separate action, addresses the infringing drug coating Cordis uses on its drug-eluting stent. Cordis does not come to this Court with clean hands, and does not warrant the extraordinary equitable relief it seeks.

### III. ARGUMENT

As this Court has explained, "a preliminary injunction constitutes extraordinary relief." *Scimed Life Sys., Inc. v. Johnson & Johnson*, No. CIV A 00-404-SLR, 2001 WL 652027 at \*1 (D. Del. Mar. 29, 2001). The Federal Circuit has echoed this principle, stating that a preliminary injunction is "a drastic and extraordinary remedy that is not to be routinely granted." *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993) (citing *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991) and *Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 683 (Fed. Cir. 1990)).

Accordingly, to obtain a preliminary injunction, Cordis must demonstrate that:

- 1) it has a reasonable likelihood of success on the merits;
- 2) it would suffer irreparable harm if the injunction were not granted;
- 3) the balance of relative hardships tips in its favor; and
- 4) an injunction would not have a negative impact on the public interest.

*Scimed Life Sys.*, 2001 WL 652027 at \*1; accord *New England Braiding Co., Inc. v. A.W. Chesterton Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992). Cordis cannot establish any of these factors, much less all of them.

Given that Cordis has restricted its motion to allegations of literal infringement of Claim 23 of the '762 patent, BSC shall similarly restrict this preliminary response.

#### A. **Cordis Is Unlikely To Succeed On The Merits**

Cordis is unlikely to succeed on the merits because, among other reasons, the EXPRESS stent does not infringe Claim 23 as properly construed. Moreover, if Claim 23 is stretched to encompass the EXPRESS stent, that claim would be invalid.

### 1. The EXPRESS Stent Does Not Literally Infringe Claim 23

"To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly." *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). If even one claim limitation is missing from the accused device, there is no literal infringement. *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999) (citations omitted). Cordis cannot meet this standard.

Prior to comparing the limitations set forth in a claim to an accused product, the Court must first construe the meaning of those limitations as a matter of law. *Id.* at 976 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996)). This Court has already construed aspects of a number of limitations found in Claim 23 in prior litigations.

Under these constructions, the EXPRESS stent does not literally infringe Claim 23. For example, the EXPRESS stent does not meet the Court's previous construction of the "substantially uniform thickness" limitation as requiring that:

The thickness at all points along the wall surface of the tubular member, both at its first and second diameters, must be substantially the same. Variances as little as .001 inches fall outside the scope of "substantially uniform."

*Cordis Corp. v. Medtronic AVE, Inc.*, 194 F. Supp. 2d 323, 332 (D. Del. 2002). The struts of the EXPRESS stent vary in thickness by more than .001 inches at points along the wall surface. Accordingly, the EXPRESS stent does not meet the "substantially uniform thickness" limitation as previously construed by this Court and does not literally infringe Claim 23.

In addition to Cordis' inability to prove infringement under this Court's prior claim constructions, it is also unlikely to be able to prove infringement of additional aspects of claim limitations that were not previously construed. For example, Cordis is unlikely to be able

to prove that the EXPRESS stent is "thin-walled." While the Court did construe aspects of this claim limitation in prior litigation, it was not requested to construe an aspect of the limitation relevant here: whether a strut that is thicker than it is wide is "thin-walled." BSC believes that construction of this aspect of the limitation is now necessary. Cordis' admissions and concessions during prosecution, among other things, preclude a construction that captures struts such as those found in the EXPRESS stent.

As a further example, Cordis is unlikely to be able to prove that the EXPRESS stent has a "wall surface." While the Court construed aspects of this claim limitation in prior litigation, it again was not requested to construe an aspect of the limitation relevant here: whether a stent without at least one elongate member running from one end of the stent to the other has a "wall surface." BSC believes that construction of this aspect of the limitation is now necessary. The specification of the '762 patent, among other things, precludes a construction that captures stents such as the EXPRESS.

Further—and to the extent that the Court revisits the claim limitation "slots"—Cordis is unlikely to be able to prove that the EXPRESS stent meets any revised construction of that limitation.

For at least these reasons, which BSC will develop through further investigation, discovery and submissions, Cordis is unlikely to prove that the EXPRESS stent literally infringes Claim 23.

## **2. If Stretched To Ensnare The EXPRESS Stent, Claim 23 Is Invalid**

If Claim 23 is stretched to encompass the EXPRESS stent, that claim is invalid under, *inter alia*, 35 U.S.C. §§ 102 and 112. For example, 35 U.S.C. § 102(f) provides that a patent is invalid if the person seeking it "did not himself invent the subject matter sought to be patented." Dr. Palmaz "did not himself invent" the subject matter exemplified by the EXPRESS

stent. As a result, to the extent Claim 23 is stretched to encompass that subject matter, and thereby ensnare the EXPRESS stent, that claim is invalid under § 102(f).

Any attempt to stretch Claim 23 to include such subject matter also runs afoul of 35 U.S.C. § 112. For example, under § 112, a patent specification must sufficiently describe the claimed invention so that one of ordinary skill in the art would recognize, upon reviewing the patent, that the inventor actually invented what is claimed with all of its limitations. *See, e.g., Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998). And as the Federal Circuit has explained, "one cannot describe what one has not conceived." *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993). Upon reviewing the '762 patent, one of ordinary skill in the art would not recognize the subject matter exemplified by the EXPRESS stent, much less believe that Dr. Palmaz invented it. That is fatal under § 112.

Under § 112, a patent specification must also "enable those skilled in the art to make and use the full scope of the claimed invention without undue experimentation." *National Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195-96 (Fed. Cir. 1999) (citations omitted); *accord Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339 (Fed. Cir. 2003). Compliance with this requirement is judged as of a patent specification's filing date. *Plant Genetic*, 315 F.3d at 1339. The '762 patent did not enable those of ordinary skill in the art at the relevant time to make the subject matter exemplified by the EXPRESS stent without undue experimentation. That is also fatal under § 112.

For at least these reasons, which BSC will develop through further investigation, discovery and submissions, Cordis is unlikely to sustain the validity of Claim 23 if that claim is stretched to encompass the EXPRESS stent.

Cordis' inability to prove a reasonable likelihood of success on the merits will be enough to warrant denial of its motion for a preliminary injunction. *See New England Braiding*, 970 F.2d at 882 (affirming denial of a preliminary injunction even though the trial court did not make findings with respect to the other three factors). But Cordis will fail with respect to the other preliminary injunction factors as well.

**B. Cordis Will Not Be Irreparably Harmed Absent A Preliminary Injunction**

Cordis cannot establish irreparable harm absent a preliminary injunction. A presumption of irreparable harm arises only if the movant makes a *clear showing* of likely success on the merits. *See, e.g., Nutrition 21*, 930 F.3d at 871 (stating that "without a clear showing of validity and infringement, a presumption of irreparable harm does not arise in a preliminary injunction proceeding"). As this Court has explained, a reasonable showing of likely success on the merits is not enough to presume irreparable harm; such a showing must be accompanied by "a separate showing of irreparable injury." *Upjohn Co. v. Riahom Corp.*, 641 F. Supp. 1209, 1217 (D. Del. 1986).

Cordis will not be able to make a clear showing of likely success on the merits. As a result, Cordis will not be entitled to a presumption of irreparable harm. But even if it were, no less than four facts would rebut such a presumption, just as they preclude Cordis from making "a separate showing of irreparable injury" absent the requested injunction.

**1. Cordis Delayed For Over Sixteen Months Before Seeking A Preliminary Injunction**

"[D]elay in seeking a remedy is an important factor bearing on the need for a preliminary injunction." *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995). As the Federal Circuit has explained, "[a]bsent a good explanation . . . 17 months is a substantial period of delay that militates against the issuance of a

preliminary injunction." *Id.* (citing cases determining that delays ranging from 7½ to 15 months undercut claims of irreparable harm).

Here, Cordis delayed for over sixteen months before moving for a preliminary injunction. That delay contradicts any assertion of the requisite irreparable harm.

## 2. Cordis Has Offered To License And Licensed The '762 Patent

Granting a license under a patent is "incompatible with the emphasis on the right to exclude" sought to be enforced by a preliminary injunction. *T.J. Smith & Nephew Ltd. v. Consolidated Med. Equip., Inc.*, 821 F.2d 646, 648 (Fed. Cir. 1987) (affirming denial of a preliminary injunction). As the Federal Circuit has explained, sales lost to an alleged infringer are no less compensable in dollars than sales lost to a licensee. *Illinois Tool Works*, 906 F.2d at 683 (affirming denial of a preliminary injunction). Even one offer to license indicates that a patentee "is willing to forgo its patent rights for compensation. That evidence suggests that any injury suffered . . . would be compensable in damages." *High Tech*, 49 F.3d at 1557 (reversing grant of a preliminary injunction). In short, a license or offer to license confirms the adequacy of monetary compensation and contradicts any assertion of irreparable harm absent a preliminary injunction.

Here, Cordis has both offered to license and licensed the '762 patent. At this time, BSC is aware of at least one such offer to license and one such license. The offer to license was made to BSC as part of settlement discussions in prior litigation. And the license allows Guidant and its affiliate Advanced Cardiovascular Systems to practice the '762 patent, among other patents. Cordis' offer to license and license of the '762 patent contradicts any assertion of the requisite irreparable harm.

### 3. Non-Infringing Alternatives Exist

The existence of non-infringing alternatives undercuts any assertion of irreparable harm absent a preliminary injunction. *See Rosemount, Inc. v. ITC*, 910 F.2d 819, 821 (Fed. Cir. 1990) (affirming ITC denial of temporary relief). The existence of such alternatives establishes that, regardless of whether such an injunction is granted, the patentee will have to compete in the marketplace and cannot rely on any asserted right to exclude.

This Court has already found that Medtronic AVE sells stents that do not infringe the '762 patent. *Cordis Corp.*, 194 F. Supp. 2d at 368. And Cordis states that "Cordis *and others* easily can fill the demand for existing types of bare metal stents" should BSC be preliminarily enjoined. (Cordis Br. at 15) (emphasis added) The existence of these non-infringing alternatives – which this Court has found and Cordis has admitted – contradicts any assertion of the requisite irreparable harm.

### 4. Monetary Damages Would Adequately Compensate Cordis For Any Infringement

The availability of adequate monetary damages weighs heavily against a claim of irreparable harm absent a preliminary injunction. *See Sampson v. Murray*, 415 U.S. 61, 90 (1974). "[T]here is *no presumption* that money damages will be inadequate in connection with a motion for an injunction pendente lite. Some evidence and reasoned analysis for that inadequacy should be proffered." *Nutrition 21*, 930 F.2d at 872 (emphasis added). Cordis cannot proffer any such evidence and analysis.

Monetary damages adequate to compensate Cordis for prior alleged infringement of the '762 patent were calculated by juries on two prior occasions. *Cordis Corp.*, 194 F. Supp. 2d at 338-39. Thus, any argument that monetary damages here are inadequate or

beyond calculation is contradicted by the facts. And Cordis has not even suggested that BSC would be unable to pay monetary damages for the alleged infringement of the '762 patent.

For at least these reasons, which BSC will develop through further investigation, discovery and submissions, Cordis will not be able to establish irreparable harm absent a preliminary injunction.

Cordis' inability to establish the requisite irreparable harm will be enough to warrant denial of its motion. As the Federal Circuit has explained, "a movant cannot be granted a preliminary injunction without findings by the district court that the movant carried its burden on *both* factors" of likelihood of success on the merits and irreparable harm. *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1556 (Fed. Cir. 1994) (emphasis in original). A district court need not even articulate findings on the other requirements for a preliminary injunction "when the court *denies* a preliminary injunction because a party fails to establish *either* of the two critical factors." *Id.* (emphasis in original). Review of the two remaining preliminary injunction factors, however, confirms that Cordis will not be able to establish either of them.

### C. The Balance Of The Hardships Does Not Favor An Injunction

As with the other factors, Cordis cannot establish that the balance of hardships tips in its favor. Cordis argues that the expiration of the '762 patent in 2005, and BSC's awareness of that patent, somehow tip the balance in its favor. But these arguments are meritless. First, as commentators have explained, "[t]he length of time before expiration of the patent in question seems to be treated by the courts as a neutral factor." *Chisum on Patents* § 20.04[1][e][ii] (2002). The Federal Circuit has confirmed this view, rejecting the argument that the need for a preliminary injunction increases as a patent nears its expiry. *See, e.g., Woodard v. Sage Prod., Inc.*, 818 F.2d 841, 854 (Fed. Cir. 1987).

BSC's awareness of the '762 patent is similarly irrelevant. As discussed above, the EXPRESS stent is not likely to infringe any valid claim of the '762 patent. As a result, Cordis' theoretical hardship arguments and cited cases are inapposite.

The balance of real-world hardships tips in BSC's favor. For example, if a preliminary injunction were granted, Cordis may or may not sell more stents given the existence of non-infringing alternatives. Such an injunction, however, would require BSC to shut down its EXPRESS stent manufacturing line in Minnesota, costing hundreds of jobs. Courts have long recognized that this type of hardship can tip the balance in favor of a defendant. *See, e.g., Essex Hosiery Mfg. Co. v. Dorr*, 8 F. Cas. 791, 792 (C.C.D. Mass. 1846) ("The defendants had a manufacturing establishment, of more than \$100,000 capital, and employing more than a hundred workmen. An injunction, by arresting their business, would produce great mischief, for which, if the suit should terminate in their favor, there would be no remedy."); *American Cyanamid Co. v. U.S. Surgical Corp.*, 833 F. Supp. 92, 133 (D. Conn. 1992) (denying preliminary injunction and finding that the potential for job losses by the accused infringer if a preliminary injunction were granted was greater than the potential for job losses by the patentee absent the injunction).

For at least these reasons, which BSC will develop through further investigation, discovery and submissions, Cordis will not be able to establish that the balance of hardships tips in its favor.

#### **D. The Requested Preliminary Injunction Is Not In The Public Interest**

In addition to its inability to establish the other three preliminary injunction factors, Cordis cannot establish that the requested injunction is in the public interest. In connection with this factor, Cordis seeks to rely on perfunctory pronouncements regarding a public interest in the patent system. But that is not enough. As the Federal Circuit has

explained, the proper focus "should be whether there exists some critical public interest that would be injured by the grant of preliminary relief." *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1458 (Fed. Cir. 1988).

Such an interest exists here: the public's interest in a competitive medical device market that allows patients and health care professionals to choose the safest and most effective treatment possible in each case. Recognizing this interest, this Court has stated in prior stent litigation between the parties that it "is not inclined to enter injunctive relief on a preliminary basis in this or any similar case, given the public's interest in a competitive medical device market." *Scimed Life Sys.*, 2001 WL 652027 at \*1. Other courts have reached similar conclusions.

For example, in *Scripps Clinic & Research Found. v. Genentech, Inc.*, the court found that the public has an interest in access to the best possible medical treatments. 666 F. Supp. 1379, 1401 (N.D. Cal. 1987), *aff'd*, 927 F.2d 1565 (Fed. Cir. 1991). The court found this interest so compelling that the mere possibility that the accused product could prove superior "counsel[ed] against granting a preliminary injunction." *Id.* (denying a preliminary injunction where the accused infringer's blood-clotting protein was potentially safer and more economical than other such proteins). Similarly, in *Datascope Corp. v. Kontron, Inc.*, the court found that public harm was shown where "some physicians prefer defendant's [product]." 611 F. Supp. 889, 895 (D. Mass. 1985), *aff'd*, 786 F.2d 398 (Fed. Cir. 1986).

Cordis' requested injunction would harm this recognized public interest for a number of reasons. For example, the requested injunction would remove a bare-metal stent that many physicians prefer from the market. Many physicians prefer BSC's EXPRESS stent to Cordis' Bx VELOCITY stent because, among other reasons, it is more flexible and easier to

deliver to patients. Data support this preference, showing that fewer patients receiving EXPRESS stents experience a re-narrowing of the stented area (so-called restenosis) than those receiving Bx VELOCITY stents. (Exhibit D) Indeed, the Bx VELOCITY stent has been publicly criticized by doctors as, among other things, "a lousy base stent," a stent that "fares very poorly against current-generation stents" and a stent that is "harder to get where . . . it needs to go in the vessel." (Exhibit E at 5-6)

In an effort to divert attention from the problems with its Bx VELOCITY stent, Cordis speculates about the future prospects for its proposed drug-eluting stent, CYPHER. But CYPHER is the same "lousy base stent." The only difference is that, for CYPHER, the base Bx VELOCITY stent is covered with two polymers and the drug sirolimus. As a result, CYPHER suffers the same drawbacks as its base Bx VELOCITY stent.

Cordis claims that the two polymers and sirolimus drug on CYPHER will help overcome these drawbacks – such as the high restenosis rates for the Bx VELOCITY stent – but these substances raise safety and efficacy issues of their own. For example, the sirolimus drug Cordis uses to coat the Bx VELOCITY stent has caused several deaths at higher doses in other applications not approved by the FDA. (Exhibit F) Moreover, the undercoat polymer Cordis uses to bind the sirolimus drug to the Bx VELOCITY stent can cause inflammation of vascular tissue. (Exhibit G) As a result, it is far from certain that CYPHER will prove to be the advance Cordis predicts.

Indeed, Cordis' clinical studies have already raised red flags regarding CYPHER. For example, Cordis is now conducting a new clinical study to investigate the proper dose of sirolimus for use with each CYPHER stent, its so-called REDOX study. The timing of this

clinical study indicates that Cordis may still be using too much sirolimus on each CYPHER stent.

Clinical data that Cordis has publicly presented to date also raise red flags regarding CYPHER. For example, such data show that a CYPHER stent can lead to various problems in patients, including: incomplete apposition to the vascular tissue in which it is inserted; undesirable effects on the vascular tissue on either side of the inserted stent (so-called edge effects); and aneurysms.

With respect to incomplete apposition, public clinical data show that a CYPHER stent may not conform completely to the vascular tissue in which it is inserted. This incomplete apposition may disrupt blood flow and lead to dangerous blood clots. This situation is especially perilous when, as seen in a Cordis presentation, it occurs in connection with remodeling of the vascular tissue away from the stent. (Exhibit H at 3) When this occurs, the inside of the artery literally changes its shape to pull away from the stent. Such a situation can lead to dangerous blood clots and aneurysms, such as the aneurysm identified in Cordis' data. *Id.* at 4.

Another red flag for CYPHER is that some doctors apparently believe its base Bx VELOCITY stent is incompatible with the type of vascular damage best addressed by its sirolimus drug coating. Specifically, some doctors apparently "are worried about their ability to deliver a relatively stiff 2.5 mm CYPHER stent to the small diameter locations where it would likely do the most good." (Exhibit I at 24)

In contrast to CYPHER, BSC's proposed drug-eluting stent, TAXUS, is based on a preferred bare-metal stent, uses paclitaxel instead of sirolimus as the active drug and avoids the Cordis undercoat polymer that may inflame vascular tissue. For these reasons, among others, BSC believes that TAXUS is superior to CYPHER and will become the standard of care for

drug-eluting stents. Indeed, the FDA has determined that TAXUS may represent "a breakthrough technology." (Exhibit J)

At this point, however, it is too soon to tell which drug-eluting stent will prevail. The TAXUS stent is still in a large clinical trial. And the CYPHER stent, even if approved by the FDA, has too many red flags to ignore. This Court has recognized "the public's interest in a competitive medical device market." That interest is best served by letting patients and their healthcare professionals evaluate CYPHER, TAXUS and the available bare-metal stents and choose the safest and most effective stent possible in each case. Cordis seeks to eliminate that choice, without a trial on the merits, to increase its profits. That is not in the public interest.

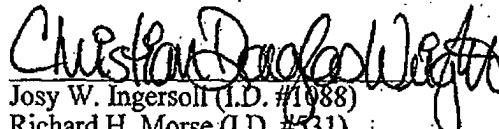
For at least these reasons, which BSC will develop through further investigation, discovery and submissions, Cordis will not be able to establish that its requested preliminary injunction is in the public interest.

**IV. CONCLUSION**

For at least the reasons highlighted above, once the Court has had a chance to consider all of the facts and legal issues on a fully developed record, and has conducted a preliminary injunction hearing, BSC has confidence that Cordis will not be able to justify the extraordinary relief it seeks.

Dated: March 14, 2003

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**CERTIFICATE OF SERVICE**

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